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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MILLER, CHERYL L

ART UNIT PAPER NUMBER

3738

DATE MAILED: 12/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/986,775

Applicant(s)

PEYMAN, GHOLAM A.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28, 30-31, 33-34, and 36-44 is/are rejected.
- 7) ☒ Claim(s) 29 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 28-44 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36, and 37-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37 is unclear in lines 3 and 4. Claim 37 recites, "marking markings" and "that indicates extend along" and "to align aligning with". Appropriate correction is required. Claims 38-44 depend upon claim 37 and inherit all problems with the claim. It is noted to the applicant that claims 42 and 43 contain similar errors. Claim 42 recites, "marking markings" in line 3 and claim 43 recites, "claim 37 38," in line 1 and "are is" in line 2.

Claim 36 recites the limitation "said markings" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether applicant is referring to the inlay markings or sheet markings, since both are referred to as markings.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 34 and 42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Portions of the body are considered non-statutory subject matter. Claim 34 recites, "said first and second surfaces of said cornea.", where the applicant has positively claimed the cornea and cornea surfaces, which are non-statutory subject matter. Claim 42 recites, "said corresponding marking markings on the surface of the cornea.", where the applicant has claimed markings in combination with the cornea, which is non-statutory subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 37, 41, 42, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Reynolds (USPN 4,452,235, cited by applicant in IDS). Referring to claim 37, Reynolds discloses an inlay (47) comprising a first and second surface, and removable markings (81, fig. 11, removable marking is a target image and is inherently removable) on one surface (markings directed onto the surface of the cornea and hence, also the inlay, col.9, lines 13-22) indicating and extends along at least one radial axis (grids make take the form of radial meridians, col.7, line 60-col.8, line 7). Referring to claims 41-42, Reynolds discloses an inlay that is asymmetric (col.6, lines 45-47) and transparent (col.6, lines 40-42). Referring to claim

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44, Reynolds discloses an inlay (47) having a center mark and at least two radial axes extending from the center to the periphery of the inlay (81, fig. 11; col.8, lines 3-6).

Claims 37, 41, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Nigam (USPN 6,102,946, cited by applicant in IDS). Referring to claim 37, Nigam discloses an inlay (74) comprising a first surface, second surface, and removable markings (protrusions 76a, 76b, or ink markings; col.2, lines 50-56, in the direction of the cylindrical axis; col.6, lines 35-44 visual indicators such as markings; col.8, lines 31-34, 45-46, ink markings; protrusions 76a, 76b, both extend along a radial axis in fig. 13) on a surface indicating and extending along at least one radial axis. Since the markings may be in ink, or protrusions, it is inherent that the markings may be removed, by sanding, resurfacing, or dissolution over time. Referring to claims 41-42, Nigam discloses an asymmetric (col.6, lines 12-30) and transparent inlay (col.2, lines 65-67; col.6, lines 31-32).

Claims 37, 38, 41, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Nigam (Pub. No. US 2002/0029981 A1, cited in previous office action). Referring to claims 37, and 38, Nigam discloses an inlay (40, 92) comprising a first surface, second surface, and a removable sheet of material (45) directly overlaying the second surface (figs. 14b-14d), the sheet having markings (22, 23, 24, 29) thereon for positioning (0042, 0043, 0049) and removable markings (94) on the inlay (figs. 18-20; 0070, 0071, inherently the markings are removable since they are engraved, or printed with ink, they may be removed by sanding, resurfacing, or the ink may dissolve over time), that indicate and extend along at least one radial axis (Nigam discloses markings used in a clockwise orientation or any other symmetrical or asymmetrical orientation, 0070)). Referring to claim 41, Nigam discloses an asymmetric inlay (figs. 18-20; asymmetric

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0070, 0071; astigmatism 0002, 0004). Referring to claim 42, Nigam discloses a transparent inlay (0002, 0005).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 30, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choyce (USPN 4,655,774, cited by applicant in IDS). Referring to claim 28, Choyce discloses an inlay (10) comprising a first surface, second surface, and a removable sheet of material (instrument, fig. 5, col. 2, lines 63-68) overlaying the second surface (sheet is structurally the same as claimed and capable of directly overlaying the inlay, depending on the procedure, how much the flap is pulled back), the sheet having markings (markings being the inner boundaries or edges of the instrument) thereon for positioning or removable markings on the inlay. Choyce does not disclose the sheet of material to be a pliable material. It is well known in the field of implants to use non-rigid pliable materials to prevent or decrease the possibility of trauma during implantation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a sheet of material made of a pliable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

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Referring to claims 30 and 31, Choyce discloses an asymmetric inlay for correcting astigmatic error (col.1, lines 7-9, 42-46) and the inlay being transparent (clear portion, col.1, lines 30-31, 47-53; col.2, line 17).

Referring to claim 33, Choyce discloses a pliable inlay for positioning between surfaces of the cornea (fig.3a-4).

Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nigam (Pub. No. US 2002/0029981 A1, cited in previous office action). Nigam discloses markings on an inlay (40) and removable sheet (45) used for the same purpose of aligning and positioning the inlay (0042, 0043, 0049, 0054, 0070, 0071), the markings on the sheet having a center mark (23) and outer marks (22, 24, 29), however does not disclose the markings being radial axes extending from the center to the periphery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to mark the sheet with radial axes instead of radial circles or holes, since both serve the same purpose of alignment and angular positioning, as such would merely constitute substitution of functionally equivalent markings.

Allowable Subject Matter

Claims 29, 34, 35, 36, and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 34, 36, and 43 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and 101 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Cheryl Miller


BRUCE SNOW
PRIMARY EXAMINER